

Application No.: 10/010,715

REMARKS

Claims 1-35 are pending. By this Amendment, claims 1, 13, 21, and 25 are amended.

The Office Action has objected to the use of certain trademarks in the specification. Accordingly, the specification has been revised to show known trademarks in all-capital letters. Pursuant to MPEP 608.01(v) it is believed that, in this country, their meanings are well-known and satisfactorily defined in the literature. Therefore withdrawal of this objection is requested.

Claims 1-12 and 21-27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hubbell et al. (U.S. Patent No. 5,410,016) in light of Rhee et al. (U.S. Patent No. 5,874,500) and Hsu et al. (U.S. Patent No. 5,192,743). It is unclear what combination of these references is applied against which claims. It is understood that Hubbell et al. is applied against claims that are missing the element of certain kits and of crosslinked hydrophilic polymers having chemical crosslinks identifiable as products of an electrophilic-nucleophilic reaction, wherein the crosslinked hydrophilic polymers comprise certain chemical compositions. To provide one of the missing elements, the Office Action applies Rhee et al against claims 2-4, 6-8, 12, 23, and 26 so that it is understood that the combination of Hubbell et al. and Rhee et al. is applied against these claims. It is stated that Hsu et al. is applied against claims 21-23 in light of the combined references so that it is understood that the combination of Rhee et al., Hubbell et al., and Hsu et al. is applied against these claims. The remaining claims 1, 5, 9-11, 24-25, and 27

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are therefore believed to be rejected in light of only Hubbell et al. Clarification of the proposed combinations of references is respectfully requested so that the Applicant can fully address the concerns of the Examiner and thereby expedite prosecution.

A prima facie case of obviousness requires that each element of the claimed invention must be taught or suggested by the prior art. MPEP 2143 Further, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. MPEP 2143. And, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. MPEP 2143, emphasis added.

With respect to the claims rejected in light of Hubbell et al., which are believed to be claims 1, 5, 9-11, 24-25, and 27, it is noted that claims 1-11, 25, and 27 are directed to a visualization agent that reflects or emits light at a wavelength detectable to a human eye to thereby provide a means for visualization of the coating. The underlined portion has been added to claims 1 and 25 so as to clarify, without narrowing, that the visualization agent provides a means for visualizing the coating. And claim 24 also has an element of "means for visualization".

It is respectfully pointed out that there can be no prima facie case of obviousness because the cited references do not teach or suggest all of the claimed elements, e.g., a visualization agent in a hydrogel. The Office Action has pointed to Hubbell et al. as teaching the use of various dyes and/or photoinitiators, e.g., col. 9, lines 20-63 as

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teaching, e.g., eosin dye, various acetophenones, acridines, rose Bengal, and phenazines such as methylene blue. These dyes/initiators are taught as being useful for photoinitiation, e.g., see header at col. 9 line 20, and as being photooxidizable and photoreducible, e.g., at col. 9 line 52, with the choice of the dye/photoinitiator being dependent on the photopolymerizable regions, e.g., col. 9 line 35.

All of the inventors of Hubbell et al., however, teach in U.S. Patent No. 6,632,446 that use of these dyes/initiators in photoinitiated systems results in the effective destruction of the dyes/photoinitiators so that they are no longer effective as visualization agents: "The dye bleaches after illumination and reaction with amine into a colorless product, allowing further beam penetration into the reaction system".<sup>1</sup> Thus a person of ordinary skill in these arts would understand Hubbell et al. as teaching that dyes/photoinitiators used for initiation of polymerization and would become bleached to produce a colorless product. Apparently, the initiator is broken down to provide initiation of polymerization. Since Hubbell et al. teaches that there would be no visualization agent in the hydrogels, Hubbell et al. can not teach or suggest the element of a visualization agent in a hydrogel and there can be no *prima facie* case of obviousness. Therefore withdrawal of 35 U.S.C. § 103(a) rejections in light of Hubbell et al. is requested for all of the claims, including claims 1, 5, 9-11, 24-25, and 27.

<sup>1</sup> This quote, with additional context: "Dye-sensitized polymerization is well known in the chemical literature . . . After absorbing the laser light, the dye is excited to a triplet state. The triplet state reacts with a tertiary amine such as the triethanolamine, producing a free radical which initiates the polymerization reaction. . . Photoinitiating Dyes [Heading] Any dye can be used which absorbs light having a frequency between 320 nm and 900 nm, can form free radicals, is at least partially water soluble, and is non-toxic to the biological material at the concentration used for polymerization. There are a large number of photosensitive dyes that can be used to optically initiate polymerization, such as ethyl eosin, eosin Y, fluorescein, 2,2-dimethoxy-2-phenyl acetophenone, 2-methoxy-2-phenylacetophenone, camphorquinone, rose bengal, methylene blue, crythrosin, phloxime, thionine, riboflavin, methylene green, acridine orange, xanthine dye, and thioxanthine dyes. [ ¶ break omitted] The preferred initiator dye is ethyle eosin due to its spectral properties in aqueous solution . . . The dye bleaches after illumination and reaction with amine into a colorless product, allowing further beam penetration into the reaction system. U.S. Patent No. 6,632,446, col. 7, lines 7-42.

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Moreover, there would be no motivation to combine Hubbell et al. with another reference to produce a hydrogel with a visualization agent. Hubbell et al. teaches that removal of the color is desirable to enhance penetration of the polymerizing light, as quoted above. The addition of a visualization agent would be contrary to the teaching to remove color from the hydrogels. Therefore Hubbell and Rhee can not be combined to make a *prima facie* case of obviousness. As indicated, it is believed that a combination of Rhee et al. and Hubbell et al. has been indicated in the Office Action for claims 2-4, 6-8, 12, 23, and 26. Therefore the withdrawal of the rejections of these claims under 35 U.S.C. § 103(a) is requested.

Claim 21 was amended without narrowing to clarify that the visualization agent in the kit would be a visualization agent in the hydrogel formed using the kit. The Office Action indicates that Hubbell et al. was combined with other references to make the *prima facie* case for the 35 U.S.C. § 103(a) rejection. Since Hubbell et al. may not be properly combined with the other references to make a hydrogel having a visualization agent, the withdrawal of this rejection is respectfully requested.

The Office Action points to Rhee et al. as providing imaging agents such as iodine or barium sulfate, or fluorine in order to aid visualization of the composition. Rhee et al. states, at col. 10, lines 63-67, that. "The crosslinked polymer compositions can also be prepared to contain various imaging agents such as iodine or barium sulfate, or fluorine, in order to aid visualization of the compositions after administration via X-ray, or <sup>19</sup>F-MRI, respectively." X-ray and MRI are not directed to reflecting or emitting light at a wavelength detectable to a human eye. Therefore Rhee et al. do not teach or suggest visualization agents a visualization agent that reflects or emits light at a

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wavelength detectable to a human eye to thereby provide a means for visualization of the coating. Therefore there is no motivation to combine Rhee et al. with other references to provide the presently claimed visualization agents.

Claims 13-20 and 28-35 were rejected under 35 U.S.C. 103(a) in light of Hubbell et al. and Rhee et al. Claim 13 has been amended without narrowing to clarify that the visualization agent that reflects or emits light at a wavelength detectable to a human eye thereby provides a means for visualization of the coating by a human eye. Claim 28 states that a concentration of visualization agent is selected that results in a visually observable change when the polymer composition is applied. As discussed above, Hubbell et al. teaches initiator/dyes that are rendered colorless during formation of a hydrogel. Therefore Hubbell may not be combined with other references to create a hydrogel with a visualization agent unless that agent is "colorless". Therefore there can be no *prima facie* case of obviousness and withdrawal of these rejections is requested.

The claims are directed to visualization agents detectable by a human eye. As discussed above, Rhee et al. teach the use of visualization agents for X-Ray or MRI, which are procedures that do not involve detection by a human eye. Instead, various machines are used to visualize them. Therefore there is no teaching or suggestion in Rhee of the presently claimed visualization agents. In the absence of this element, therefore, there can be no *prima facie* case of obviousness and withdrawal of this rejection is requested.

The Office Action has made an obviousness type double patenting rejection of the present claims in light of U.S. Patent No. 6,566,406 and Hubbell et al. or Hubbell et al. in combination with Hsu et al. U.S. Patent No. 6,566,406 is a parent of the present

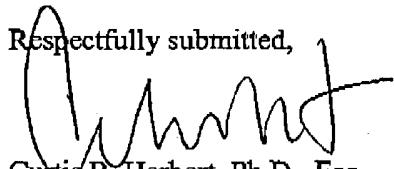
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application, has substantial disclosure of visualization agents, and may provide an effective priority date for some or all of the present claims in the application. The double patenting rejection is respectfully traversed since the claims of the 6,566,406 Patent are not directed to visualization agents.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,



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